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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM32/0914

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/888,350	07/03/97	014	CRANE, L	1623 09/14/98
First Named Applicant	OR,	YAT SUN		

TITLE OF INVENTION 6-O-SUBSTITUTED KETOLIDES HAVING ANTIBACTERIAL ACTIVITY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	5976.US.P1	514-029.000	195	UTILITY	NO \$1320.00	12/14/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.
- If the SMALL ENTITY is shown as NO:
 - A. Pay FEE DUE shown above, or
 - B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/888,350 07/03/97 OR

Y 5976.US.P1

HM32/0914

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EXAMINER

CRANE, L

ART UNIT

PAPER NUMBER

1623 8

DATE MAILED:

09/18/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to Information disclosures of 9/30/97 & 1/23/98

☒ The allowed claim(s) is/are 1-3 and 12-22

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4-5

☐ Notice of Draftperson's Patent Drawing Review, PTO-948

☒ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

88,350

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

5 Restriction to one of the following inventions is required under
35 U.S.C. §121:

10 I. Claims 4-8, drawn to 3, 9-diketo-11,12-dihydroxyerythromycin and closely related derivatives, pharmaceutical compositions thereof (linking claim 2), methods of preparing same, and their use in the treatment of bacterial infections (linking claim 3), classified in Class 514, subclass 029.000; and Class 536, subclass 007.200.

15 II. Claims 11-22, drawn to 3, 9-diketo-11,12-{methylendioxy, fused 1,3-oxazolidinyl, or fused 2-oxo-1,3-oxazolidinyl}erythromycin and closely related derivatives, pharmaceutical compositions thereof (linking claim 2), methods of preparing same, and their use in the treatment of bacterial infections (linking claim 3), classified in Class 514, subclass 029.000; and Class 536, subclass 007.400.

20 III. Claims 23-30, drawn to 3-keto-9,11-{ethylendiamino, aka fused-bridged 1,4-diazepinyl}-11,12-{fused 1,3-oxazolidinyl, or fused 2-oxo-1,3-oxazolidinyl}erythromycin and closely related derivatives, pharmaceutical compositions thereof (linking claim 2), methods of preparing same, and their use in the treatment of bacterial infections (linking claim 3), classified in Class 514, subclass 029.000; and Class
25 536, subclass 007.200.

IV. Claims 26-30, drawn to 3, 9-diketo-11,12-

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dehydroerythromycin and closely related derivatives, pharmaceutical compositions thereof (linking claim 2), methods of preparing same, and their use in the treatment of bacterial infections (linking claim 3), classified in Class 514, subclass 029.000; and Class 536, subclass 007.200.

Claims 1-3 link(s) inventions I, II, III and IV and will be examined with the elected invention to the extent to which they apply.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together,

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or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different chemical compounds and their medicinal methods of use.

Because these inventions are distinct for the reasons given above,

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and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5 During a telephone conversation with Ms. Mona Anand on August 13, 1998 a provisional election was made **with** traverse to prosecute the invention of Group II, claims **11-22** and linking claims **1-3** to the degree applicable. Affirmation of this election must be made by applicant in responding to this Office action. Claims **4-10** and **23-34** are withdrawn from further consideration by the
10 Examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. §1.143).

15 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must
20 be accompanied by a diligently-filed petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(h).

Applicant's filing of a letter of Express Abandonment on August 14, 1998 re allowed parent case US Serial Number **08/707,776** is herein noted. This action is deemed to have obviated any issue of
25 double patenting. The election made with traverse supra is deemed to have been confirmed by applicant's agreement to the following amendment wherein all non-elected subject matter has been

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cancelled.

5 An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

10 The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying this application by its Serial Number and filing date is required. See MPEP §§602.01 and 602.02. The oath or declaration is defective because:

15 It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. §120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose material information as defined in 37 C.F.R. §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part.

20 In the disclosure, the first paragraph at p. 1 of the specification was replaced by the following:

a --/This application is a continuation of U.S. Serial Number 08/707,776, filed September 4, 1996, now abandoned. {--

In the claims:

25 In claim 1, line 1, the term "selected from the group consisting of" was replaced by the term -- having the formula --.

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Claim 1 was amended by cancellation of chemical structures "II", "IV", "IV-A" and "V", and cancellation of the term "and" between now cancelled structures "IV-A and "V".

5 In claim 1, line 51, the term "selected from" was replaced with the term

-- selected from the group consisting of --.

In claim 2, a period (-- . --) was added at the end of the claim.

10 Claim 11 was cancelled as superfluous on view of the amendments to claim 1.

Claims 12 was amended by changing the term "claim 11" to read -- claim 1 --.

In claim 12, line 3, the term " ; " was replaced by the term -- : --.

15 Claims 13 was amended by changing the term "claim 11" to read -- claim 1 --.

In claim 16, at the end of line 23, the term
-- the group consisting of --

20 was inserted.

In claim 16, line 232, the term "W is absent or -NH- with " was replaced by the term -- W is absent or is -NH- with --.

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✓ In claim 16, line 234, the term "W is absent or -NH- with " was replaced by the term -- W is absent or is -NH- with --.

✓ In claim 16, line 236, the term " or " was replaced by the term -- and --.

5 ✓ In claim 17, line 237, the term " or " was replaced by the term -- and --.

✓ In claim 20, at the end of line 17, the term

10 -- the group consisting of --
was inserted.

✓ In claim 20, line 24, the term "and -S- or" was replaced by the term -- -S- and --.

15 ✓ In claim 22, at the end of line 17, the term

-- the group consisting of --

was inserted.

20 ✓ In claim 22, line 24, the term "and -S- or" was replaced by the term -- -S- and --.

✓ Claims 4-10 and 23-34 were cancelled without prejudice to the filing of divisional or continuing applications.

Authorization for this Examiner's Amendment was given in a

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telephone interview with Ms. Mona Anand on August 13 and September 10, 1998.

The following is an Examiner's Statement of Reasons for Allowance:

5 The subject matter of the instant claims is entirely included within the claims allowed in parent case **08/707,776** (compounds, pharmaceutical compositions and methods of treating bacterial infections), with the exception of methods of making claims. The claims directed to methods of making are limited to the synthesis of
10 compounds the allowability of which was already established in the parent case. Therefore, the finding of allowable subject matter in the parent case is deemed to render the instant claims allowable without further prosecution.

15 Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

20 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines now operated by Group 1600 are **(703) 308-4556 and (703) 305-3592**.

25 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L.

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E. Crane whose telephone number is 703-~~308-4639~~ . The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703)-308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-~~308-1235~~ .

10

LECrane:lec
9/13/98



MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800 *1623*



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO./TITLE
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DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
 - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
 - b. ☐ believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
 - c. ☐ acknowledges the duty to disclose information which is material to the examination of the application in accordance with 37 CFR 1.56(a).
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☒ does not state that the person making the oath or declaration acknowledges the duty to disclose material information as defined in 37 CFR 1.56(a) which occurred between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☐ Other:

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by 37 CFR 1.41(a).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☐ Other: